DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Karl Storz Endoscopy-America, Inc.
Mr. Kevin Kennan
Senior Regulatory Affairs Specialist
600 Corporate Pointe
Culver City, CA 90230

JUL 27 2015

Re: K000769
Trade/Device Name: Karl Storz MANHES Pneumotrocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated (Date on orig SE ltr): March 3, 2000
Received (Date on orig SE ltr): March 9, 2000

Dear Mr. Kennan,

This letter corrects our substantially equivalent letter of June 1, 2000.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000769

Device Name: KSEA MANHES Pneumotrocar

Indications for Use: These instruments are manually operated surgical devices intended for making incisions into the patient's body to establish pneumoperitoneum and allow insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000769

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

K000769

JUN - 1 2000

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

**Applicant:**

Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 410-2769

**Contact:**

Kevin Kennan
Senior Regulatory Affairs Specialist

**Device Identification:**

Common Name:
Trocar and Veress Needle

Trade Name: (optional)
Karl Storz MANHES Pneumotrocar

**Indication:** The KSEA MANHES Pneumotrocars are intended for making incisions into the patient's body to establish pneumoperitoneum and allow insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures.

**Device Description:** The Karl Storz MANHES Pneumotrocars are manually operated surgical devices. The body contact portions of the KSEA Plastic Trocars are composed of surgical grade stainless steel which is commonly used in medical devices for a wide range of applications and has a long history of biocompatibility for human use.

**Substantial Equivalence:** The Karl Storz MANHES Pneumotrocars are substantially equivalent to the predicate devices since the basic features and intended uses are similar. The minor differences between the Karl Storz MANHES Pneumotrocars and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: _____

Kevin Kennan
Senior Regulatory Affairs Specialist